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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/079,949	02/19/2002	Ebrahim Zandi	13761-7064	6542

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EXAMINER	
PROUTY, REBECCA E	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 12/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/079,949	ZANDI ET AL.	
	Examiner	Art Unit	
	Rebecca E. Prouty	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) *24-40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Applicant's election without traverse of Group I, Claims 1-23 in the response filed 10/4/04 is acknowledged.

Claims 24-40 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse the response filed 10/4/04.

Claims 4-9, 14-16, 22 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 is confusing in the recitation "said selection marker is leucine histidine, tryptophan, or uracil" as leucine histidine, tryptophan, and uracil can not be comprised within a vector. The selection markers in applicants vectors are genes which are involved in the biosynthesis of leucine histidine, tryptophan, and uracil, i.e., the HIS3 gene, the TRP1 gene, the LEU2 gene and the URA3 gene.

Claims 5 and 6 are confusing in the recitation of "said expression vectors contain a tag" and "said tag is myc, HA, or FLAG 6his" as vectors cannot comprise peptide tags. It is assumed applicants intended claim 5 to recite that the IKK subunit comprises a tag. Furthermore, it is noted that the "or" in Claim 6 should correctly to placed following "FLAG".

Claim 7 (upon which Claims 8 and 9 depend) is confusing in the recitation of "said yeast expression vectors contain an inducible promoter or a constitutive promoter" as the vectors are limited in Claim 1 (from which Claims 7-9 depend) to comprising inducible promoters.

Claim 14 lacks antecedent basis for "said IKKα" in Claim 11 and "said IKKβ" in Claim 10.

Claim 15 lacks antecedent basis for "said leu(met) vector".

Claim 16 is confusing in the recitation "wherein constitutive expression is induced under the alcohol dehydrogenase promoter" as the vectors are limited in Claim 1 (from which Claim 16 depends) to comprising inducible promoters. Furthermore, it is unclear how constitutive expression can be induced as the terms are mutually exclusive.

Claims 22 and 23 lack antecedent basis for "said purified IKK protein".

Claim 22 is confusing in the recitation of "substantially homologous to IKK isolated from wild-type cells" as the term "substantially homologous" is a relative term which renders the claim indefinite. The term "substantially homologous" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree of homology that must be present, and thus one of ordinary skill in the art would

not be reasonably apprised of the scope of the invention. Furthermore, the claim does not define what cells are the "wild-type" cells such that a skilled artisan would even know what the reference protein is.

Claims 14-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 14-16 recite two specific vectors which the specification and prior art fails to provide a sufficient description of i.e., pES 86(+) and leu(met). While pages 13-14 of the specification imply that these vectors are commercially available from Stratagene, the Stratagene web site and online catalog contains no mention of these vectors. Furthermore, the specification includes no description of the components of these vectors such that one can know how they differ from any other yeast expression vectors. The only information in the specification regarding these vectors is that pES 86(+) includes a alcohol dehydrogenase promoter and leu(met) includes a promoter that is repressed in the presence of methionine and induced by the

removal of methionine. In view of the lack of description of the elements of these two vectors, the scope of Claims 14-16 is unclear. For purposes of further examination the phrase "a met promoter from a leu(met) vector" in Claim 14 is interpreted as any promoter that is repressed in the presence of methionine and induced by the removal of methionine, the phrase "subcloned into said leu(met) vector" in Claim 15 is interpreted as subcloned into any yeast expression vector comprising a promoter that is repressed in the presence of methionine and induced by the removal of methionine and the phrase "subcloned into the pES 86(+) vector" in Claim 16 is interpreted as subcloned into any yeast expression vector comprising a alcohol dehydrogenase promoter

Claims 14-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention appears to employ novel vectors, i.e., pES 86(+) and leu(met). Since the vectors are essential to the claimed invention, they must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. The claimed plasmids' sequences are not fully

disclosed, nor have all the sequences required for their construction been shown to be publicly known and freely available. While pages 13-14 of the specification imply that these vectors are commercially available from Stratagene, the Stratagene web site and online catalog contains no mention of these vectors. The enablement requirements of 35 U.S.C. § 112 may be satisfied by a deposit of the plasmids. The specification does not disclose a repeatable process to obtain the vectors and it is not apparent if the DNA sequences are readily available to the public. Accordingly, it is deemed that a deposit of these plasmids should have been made in accordance with 37 CFR 1.801-1.809.

If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that the strain will be available to the public under the conditions specified in 37 CFR 1.808, would satisfy the deposit requirement made herein.

If the deposit is not made under the Budapest treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809, applicants may provide assurance or compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

1. during the pendency of this application , access to the invention will be afforded to the Commissioner upon request;
2. upon granting of the patent the strain will be available to the public under the conditions specified in 37 CFR 1.808;
3. the deposit will be maintained in a public repository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer; and
4. the deposit will be replaced if it should ever become inviable.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-13, 16-20, and 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Li et al or Rothwarf et al. (Reference C27 of Applicant's PTO-1449) in view of Epinat et al.

Each of Li et al. and Rothwarf et al. teach the coexpression of IKKα, IKKβ and IKKγ genes in a eukaryotic host by inserting the genes encoding each subunit fused to a tag (HA, FLAG or c-myc) into a mammalian expression vector, growing the host cell, lysing the host cell, and immunoprecipatating the IKK complexes. The only difference in the methods taught by Li et

al. and Rothwarf et al. to the methods of the instant claims is that in the instant claims the expression host used is yeast.

Epinat et al. teach that yeast is a convenient host for the reconstitution of the NF-κB system since it does not contain any endogenous NF-κB activity (see page 603) and that the reconstituted system provides an easy assay for testing stimuli or specific proteins that are postulated to be involved in NF-κB signaling (see page 609). Epinat et al. further teach expression vectors for the recombinant expression of genes involved in the NF-κB signaling pathway in yeast cells under the control of both constitutive promoters such as the *ADH1* promoter and inducible promoters such as the *GAL1* promoter. The yeast expression vectors comprise selection markers such as the *URA3* or *LEU2* genes.

As the IKK complex is well known to be part of the NF-κB signaling pathway it would have been obvious to one of ordinary skill in the art to reconstitute the IKK complex in a yeast host cells by expressing the IKK subunit genes of Li et al. or Rothwarf et al. in yeast using any known yeast expression vector or yeast expression vectors as taught by Epinat et al.

Claims 14, 15, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Li et al or Rothwarf et al. (Reference C27 of Applicant's PTO-1449) in view of Epinat et al.

as applied to claims 1-13, 126-20, and 22-23 above, and further in view of either or both of Mumberg et al. (Reference C22 of Applicant's PTO-1449) or page 23 of the 1999 Stratgene catalog.

Li et al., Rothwarf et al. and Epinat et al. are discussed above. They do not teach the specific yeast expression vectors recited in the instant claims.

Mumberg et al. teach yeast expression vectors which include a methionine repressible promoter which is inducible by growing the yeast cells in media lacking methionine.

Page 23 of the 1999 Stratagene catalog teach the pESC yeast expression vectors which designed for expression and functional analysis of eukaryotic genes in yeast and specifically designed to provide epitope tagging of the expressed proteins.

As each of Mumberg et al. and the Stratagene catalog teach vectors specifically designed for the expression of heterologous genes in yeast it would have been obvious to use these vectors, or a vector including the methionine repressible promoter of Mumberg et al. and the epitope tagging and other features of the pESC vectors for the expression of the genes of Li et al. or Rothwarf et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rebecca Prouty, Ph.D. whose telephone number is (571) 272-0937. The examiner can normally be reached on Monday-Friday from 8:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (571) 272-0928. The fax phone number for this Group is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Rebecca Prouty
Primary Examiner
Art Unit 1652